510(k) Summary
December 18, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Aggredyne, Inc., AggreGuide A-100.

1. Company making the submission:

Name:	Aggredyne, Inc.
Address:	10530 Rockley Road Suite 150 Houston, Texas 77099
Telephone: Toll Free Fax:	713-636-5996 866-800-1955 281-317-1874
Contact:	Edward R. Teitel, MD, JD, MBA
E-Mail:	eteitel@aggredyne.com

2. Device Name:

Trade/Proprietary Name:	AggreGuide A-100 and AggreGuide A-100 AA Assay
Common/Usual Name:	Aggregometer
Classification Name:	System automated platelet aggregation
Regulation Number:	864.5700
Product Code:	JOZ

3. Predicate Devices:

   The predicate is the Accumetrics VerifyNow-Aspirin Assay [K042423].

4. Description of Device:

   The AggreGuide A-100 is a laser light scattering system that detects the level of platelet aggregation induced by arachidonic acid agonist in whole blood in motion. The system consists of an instrument and a disposable assay cartridge with pre-loaded freeze dried agonist. A whole blood sample is

added to a disposable cartridge that is preloaded with freeze dried arachidonic acid agonist (AA) in a reaction chamber for an individual test. The amount of platelet aggregation is measured by detecting the laser light scattering caused by platelet aggregates. Aspirin is known to inhibit the level of platelet aggregation, or activity, when blood is mixed with arachidonic acid.

5. Intended Use Statement:

   The AggreGuide A-100 AA Assay is a qualitative system to aid in the detection of platelet dysfunction due to aspirin ingestion by those 18 years of age or older in 3.2% citrated venous whole blood using the AggreGuide A-100 instrument. For professional use. This test is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents. The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

6. Summary of the technological characteristics of the device compared to predicate device:

   The AggreGuide A-100 and Accumetrics VerifyNow® aggregometers both measure platelet aggregation in response to arachidonic acid (AA). In the presence of AA, platelets may be activated and aggregate. These aggregates occur when activated platelets in motion come into contact with other activated platelets. In both the AggreGuide A-100 and the VerifyNow® the AA is freeze dried and pre-loaded into disposable, single use cartridges. The AggreGuide detects the aggregates in whole blood as they pass by the optical window by light scattering. The VerifyNow® detects platelet aggregation at its optical window by measuring light transmittance. With the AggreGuide, the more active the platelets, the more aggregates are formed and the higher the Platelet Activity Index (PAI). With the VerifyNow®, the more active the platelets, the more light transmittance and the higher the Aspirin Reactive Units (ARU). Conversely, if the platelets are inhibited by aspirin, they are not activated by AA to form aggregates. Therefore, few, if any, aggregates form and the AggreGuide shows a low PAI, and, similarly, the VerifyNow® shows a low ARU. The AggreGuide's PAI, like the

VerifyNow's® ARU is a function of the number of aggregates that form in the blood.

7. Performance Testing:

Non-clinical testing: Non-clinical testing was carried out on the AggreGuide A-100 instrument for electrical safety and electromagnetic interference, as well as software validation against multiple standards. Non-clinical studies were also carried out to assess simple and complex precision, shelf life of the AA reagent, interfering substances, limit of blank (LOB), inter-instrument variability, and lot-to-lot variability. These studies showed that the AggreGuide A-100 System raised no safety concerns when used for the Intended Use.

Clinical testing: One hundred sixty nine (n=169) healthy subjects were screened for study of the sensitivity of the AggreGuide A-100 in identifying platelet dysfunction due to aspirin ingestion. One hundred thirty eight (n=138) subjects were given an aspirin dose of 325 mg (1 adult non-coated tablet) and tested with the AggreGuide for aspirin induced platelet dysfunction within 2 - 30 hours. The results shown in the tables below:

Site	Sensitivity	CI (95%)
All Sites	115/138 (83%)	76% - 89%

Table 1 - Sensitivity Results

Aspirin 325 mg Absent		Total
≥4 PAI (Platelet dysfunction not detected)	<4 PAI (Platelet dysfunction detected)	
151	16	167*
True Negative: 90% (151/167) 95% CI: (85%; 94%)	False Positive: 10% (16/167) 95% CI: (6%; 15%)	
*2 subjects were excluded due to inclusion/exclusion criteria		

Table 2 – Pre 325mg Aspirin

Aspirin 325 mg Present			Total
≥4 PAI (Platelet dysfunction not detected)	<4 PAI (Platelet dysfunction detected)	Missing PAI (due tp non-return)	
23	115	13	151*
False Negative: 17% (23/138) 95% CI: (11%; 24%)	True Positive: 83% (115/138) 95% CI: (76%; 89%)	Missing 9% (13/151) 95% CI: (5%; 14%)	
*16 subjects with PAI <4 at baseline were not evaluated			

Table 3 – Post 325mg Aspirin

The combination of non-clinical and clinical performance test results shows that the instrument performs in a substantially equivalent manner to the predicate.

8. The AggreGuide A-100 and the AgggreGuide A-100 AA Assay are a prescription device per 21 CFR Subpart D.

9. Conclusion:

   The AggreGuide A-100 and AggreGuide A-100 AA Assay are substantially equivalent to the predicate device based on intended use, technology and performance testing results.

Aggredyne, Inc.

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Edward R. Teitel, MD, JD, MBA
Chairman & CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

AGGREDYNE, INC.
C/O MR. J. HARVEY KNAUSS
11874 SOUTH EVELYN CIRCLE
HOUSTON TX 77071

December 20, 2013

Re: K122162
Trade/Device Name: AggreGuide A-100 and AggreGuide A-100 AA Assay
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: II
Product Code: JOZ
Dated: December 18, 2013
Received: December 19, 2013

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122162

Device Name: AggreGuide A-100 and AggreGuide A-100 AA Assay

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Leonthena R. Carrington -
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